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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,238	04/16/2004	Alison B. Lukacsko	94902.256172	9635

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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06/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/826,238	Applicant(s) LUKACSKO, ALISON B.	
	Examiner Donna Jagoe	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 2010 has been entered.

Claims 45-49 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 45-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Wassenaar U.S. Patent No. 7,060,289 B2.

Wassenaar teaches the method of reducing excessive sweating and minimizing side effects (see abstract) comprising application of a topical formulation of glycopyrrolate (an anticholinergic quaternary amine) in an aqueous solution (column 7, line 47) in a concentration that is from 0.25% to 6% (column 8, lines 29-30). Wassenaar

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teaches a case study of a patient with excessive sweating of the forehead and groin that resulted in a facial rash and fungal infection. After two weeks of topical application (to the skin surface) the chronic fungal infection of his groin and facial rash had both improved (column 8, lines 32-49). Regarding the concentration of the formulation instantly claimed, the amount of glycopyrrolate of Wassenaar is between 0.25% and 6% which is encompassed by the instantly claimed 0.0001% to about 20 % or from about 0.05% to about 5%. The claim elements appear in Wassenaar in the same configurations; an aqueous solution of glycopyrrolate in overlapping concentrations, serving the same functions; applied topically, to achieve the results suggested in prior art; treatment of a fungal infection. With regard to instant claim 45, drawn to "killing and inhibiting dermatophytic fungi and bacteria responsible for skin infection and non-pathological body malodor" these elements are disclosed in Wassenaar wherein it teaches that a fungal groin infection was improved when a 1% and 1.5% solution was applied.

No claims are allowed.

Response to Arguments

Applicant asserts that the formulation of Wassenaar would reduce populations of microorganisms on the skin which would thereby result in improvement of infections because of repeated treatments with antiseptic doses of alcohol and further asserts that the reduction of sweat can lead to less favorable conditions for microorganisms and to improvement of a fungal groin infection caused by such microorganisms. In response, it

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is noted that the instant claims now recite an aqueous solution, however, even though the transitional phrase is "containing", the alcohol or hydroalcoholic solution (see instant specification paragraph 101) is not excluded from the aqueous solution because it is an excipient or support material (as noted in instant claim 46). A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step. Further, when the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986). See also *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004). Additionally, in response to Applicant's allegation that the improvement of the prior art's fungal groin infection is due to a drier environment, the following prior art pertinent to applicant's disclosure is made of record and not relied upon. Merck Manual teaches that moisture is a risk factor, but does not teach that absence of moisture is the treatment. Treatment choices include azole type antifungal agents (see tinea cruris, pages 4-5). Applicant asserts that in the instant invention, Applicant was the first to recognize the anti-fungal properties of this class of compounds. In response, Wassenaar teaches the same antifungal properties of glycopyrrolate; the ultimate species selected in the genus of anticholinergic quaternary amines instantly claimed.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the

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references. In response, the claim elements appear in the prior art in the same configurations, an aqueous solution of glycopyrrolate, serving the same functions, applied topically, to achieve the results suggested in prior art, treatment of a fungal infection. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., treatment of "dry" skin surfaces) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further Applicant argues that the patient in Wassenaar was not cured. In response, there is no requirement for a cure in the instant claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./
Examiner
Art Unit 1619

June 3, 2010